

designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13836, Mar. 11, 2014]

### Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

#### § 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

#### § 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or rein-

surance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

(d) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim